CANCER CENTRAL CLINICAL PARTICIPANT REGISTRY (C3PR)

Installation Guide

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Introduction

This installation guide covers installing, setting up and configuring the application and databases. All of the examples included in this chapter are Windows specific.

Depending on your environment and needs, the C3PR installation may include installation of ten or more different components. The scope of this installation manual is to provide an installation guide for a typical Cancer Center installation where the National Cancer Institute (NCI) is hosting the Cancer Central Clinical Database (C3D). Instructions for the installation at the NCI are provided for completeness and to provide guidance for Cancer Centers who may want to install the NCI components locally.

Overview of C3PR	An overview of the C3PR Application is provided on the following site: http://trials.nci.nih.gov/projects/trialmanagement/c3ds_project/c3pr
	One of the main components of the C3PR Application is the Common Security Module (CSM). More information on CSM is provided on the following site: http://ncicb.nci.nih.gov/NCICB/infrastructure/cacore_overview/csm
	The C3PR Application is designed to work with C3D. More information about C3D is provided on the following site: http://trials.nci.nih.gov/projects/trialmanagement/c3ds_project/c3d
	The C3PR Application includes caCORE SDK Generated APIs. More information about caCORE SDK Generated APIs is provided on the following site: http://ncicb.nci.nih.gov/NCICB/infrastructure/cacoresdk

Minimal System Requirements

Minimal System Requirements for Cancer Center	Minimal system requirements are dependent on the number of patients, protocols and users planned. Some analysis and testing should be done to establish a performance based recommendation. Although the Application was tested on two servers, it could theoretically be installed on one server with the software identified below. It is expected that the tested environment in Table 1 would be more than adequate for a Cancer Center Installation.

- Internet connection
- Database Server with Oracle 9i
- Application Server with JBoss

The C3PR has been tested on the platform shown in Table 1.

	Windows Application Server	Windows Database Server
Model	Dell PowerEdge SC1425	Dell PowerEdge 1850
CPU	Intel® Xeon™ processor, 3.0GHz, 2MB Cache, 800MHz FSB	Intel® Xeon™ processor at 3.0GHz/2MB Cache, 800MHz FSB
Memory	1GB, DDR2, 400MHz,2X512, Single Ranked DIMMs	2GB DDR2 400MHz (2X1GB), Single Ranked DIMMs
Local Disk	80GB 7200 RPM SATA Hard Drive	146GB 10K RPM Ultra 320 SCSI Hard Drive
OS	Windows Server 2003 Standard Edition SP1	Windows Server 2003 Standard Edition SP1

Table 1 Platform Testing Environment

C3PR Software and Technology Requirements

Software Requirements

Required Software — Not Included in C3PR
You must download and install the required software that is not included with the C3PR (listed in Table 2). The software name, version, description, and URL hyperlinks (for download) are indicated in the table.

Software and documentation that *is* included with the C3PR Application is listed in Appendix I.

Software Name	Version	Description	URL
Java SE Development Kit (JDK)	1.5 Update 6	The Java SE Development Kit (JDK) includes: - The Java Runtime Environment (JRE) - Command-line development tools that are necessary developing applications	http://java.sun.com/javase/downloads/index.jsp
Oracle Database	9i	The tested configuration is for the C3PR data to reside on Oracle 9i.	http://www.oracle.com/technology/products/oracle9i/index.html

Software Name	Version	Description	URL
		In addition, the application has been tested with MS SQL Server. That installation is not covered in this manual	
MySQL Database	4.1.14	The tested configuration uses a CSM database on MySQL. CSM does support Oracle, but that is not a tested configuration.	http://downloads.mysql.com/archives.php?p=mysql-4.1&v=4.1.14
Common Security Module (CSM)	3.1	The CSM is used by the C3PR application, the C3PR Web Services, and the APIs. It is configured using the CSM User Provisioning Tool (UPT). Both the Schema and the UPT Should be installed.	http://ncicb.nci.nih.gov/download/
JBoss Application Server	4.0.2	JBoss is needed to host several application components of C3PR.	http://www.jboss.org/downloads/index
Apache Ant	1.6.2	Ant is needed to build the C3PR Application after the database scripts have been run.	http://archive.apache.org/dist/ant/binaries/
SSL Certificates		An SSL Certificate is required to use the C3D Web Services (available from a number of vendors for a fee – a URL for one vendor is identified here).	http://www.verisign.com/ssl/index.html
MS Excel and PDF Reader		Required to read reports.	

Table 2: Required Software and Technology for the C3PR

Optional Software	Optional software to use with the C3PR is listed in Table 3. The included (**Incl**.) column indicates (with a **Yes**) if the software is packaged with the Application download. **No** indicates that you must supply the software. A hyperlink is included for your reference to appropriate sources.

Software Name	Version	Description	URL	Incl.
MySQL Administration Suite	1.0.21 +	This tool assists in the administration of MySQL.	Download Site: http://mysql.mirror.anlx.net /Downloads/MySQLAdmini strationSuite/ File to download: mysql-administrator-1.0.21-win.msi	No
- Firewall - Back-up Software - Virus Protection - Web Server		No specific vendor recommendations are provided, but these items are recommended.		No

Table 3 Optional software and technology for the C3PR

NOTE:	The following Drivers are required if not already installed on JBoss. They should be placed in the JBoss Server Lib (example: jboss-4.0.2\server\default\lib): MySQL Connector/J is the official JDBC driver for MySQL: http://dev.mysql.com/downloads/connector/j/3.0.html File: mysql-connector-java-3.0.16-ga-bin.jar JDOM Driver: http://www.jdom.org/dist/binary/ File: jdom-1.0.tar.gz – extract and retrieve jdom.jar from the build directory Oracle JDBC Driver: http://www.oracle.com/technology/software/tech/java/sqlj_jdbc/index.html File: ojdbc14.jar – You need to login to OTN, select: Oracle9i Release 2 (9.2.0.8), (9.2.0.5), (9.2.0.4), (9.2.0.3), & (9.2.0.1) drivers Accept the license and you will be able to download the driver.

Installing the C3PR Application

Preliminary Considerations

BEFORE YOU BEGIN	The C3PR Application has been tested with the operating systems and hardware specified in this guide. The C3PR Application may not work If you are using variations of these operating systems or hardware.

BEFORE YOU BEGIN	The scripts included in the download include look up values, web site text, application behavior parameters, and resource locations specific to an installation at the National Cancer Institute Center for Clinical Research (CCR). These values must be customized for each cancer center. This customization activity should be executed by a team including personnel with knowledge of the processes and terminology used by the clinical staff in the registering of patients as well as personnel with the technical qualifications to modify and run the database scripts. The items requiring customization and factors to consider are provided in an appendix to this manual. C3PR looks for a data source with name "c3prDS" which should be configured prior to starting the installation.

BEFORE YOU BEGIN	Verify that the environment variables ANT_HOME and JAVA_HOME are set and that your PATH statement includes the locations of the Ant and Java binaries. For example: PATH should include C:\apache-ant-1.6.2\bin; C:\j2sdk1.4.2_06\bin.
	
	To do this in Windows:
	
	1. Select **My Computer** > **Properties** (from the shortcut menu) > **Advanced** tab.
	2. Click the **Environment_Variables**... button.
	3. **ANT_HOME** and **JAVA_HOME** must each be listed in one or the other of the panels of the dialog box. To add either, below one of the panels, click the **New** button.
	4. In the New User Variable dialog box, add the **Variable** and **Variable Value**.
	5. Examples:
	  Variable = ANT_HOME; Variable Value = C:\apache-ant-1.6.2
	  Variable = JAVA_HOME; Variable Value = C:\j2sdk1.4.2_06
	6. Verify that the **PATH** statement listed in the Environment Variables dialog box includes both the **ANT_HOME** and **JAVA_HOME** binaries and that they read as follows: **C:\j2sdk1.4.2_06\bin;C:\apache-ant-1.6.2\bin**. (To easily review these, copy them to a text editor.) If

	necessary, click the **Edit** button and enter the correct information.

Downloading the C3PR Application

SUGGESTION	For best results using these installation procedures for the C3PR Application, it is recommended that you follow the procedures described in this section with minimal deviation.

Complete the following steps to download the C3PR Application:

Step	Action
1	Go to the NCICB download web site: http://ncicb.nci.nih.gov/download/ Click C3PR Application Download link.
2	You will be prompted to provide your email, name, and institution.
3	You must also agree to the C3PR software license by clicking the box to indicate that you agree to the license terms.
4	You are now on the C3PR Download Page. Select the appropriate download and download the package to the installation location. This may take several minutes.
5	Extract the contents of the C3PR distribution zip file to your root directory. For example, if your root directory in Windows is `C:\`, then your C3PR home directory is: `C:\C3PR` **Note:** This directory name cannot contain any spaces or this will cause errors in Windows. For instance, do not place the C3PR directory in the Program Files directory.

The caCORE SDK Generated C3PR APIs Object Model

The application data can be accessed through the application or via the caCORE SDK Generated C3PR APIs which are included in the download and deployed separately. Please refer to the caCORE documentation for instructions on how to deploy and use the APIs.

NOTE:	The caCORE SDK Generated API documentation is available at the following locations: caCORE SDK Programmer's Guide ftp://ftp1.nci.nih.gov/pub/cacore/SDK/caCORE_SDK1.0_Programmers_Guide.pdf caCORE Technical Guide ftp://ftp1.nci.nih.gov/pub/cacore/caCORE3.0_Tech_Supp.pdf caCORE Web site http://ncicb.nci.nih.gov/NCICB/infrastructure/cacoresdk

Deploying and Running the C3PR Application

The C3PR Application can be configured to work with Oracle 9i or SQL Server. This installation manual only addresses the Oracle installation; however only minor changes are required for a SQL Server installation and the requirements for a SQL Server installation are provided in an Appendix to this document.

NOTE:	When entering information for use by the C3PR, no spaces are allowed in filenames or directory names.

Modifying the deploy.properties File in Windows	• The file `{home_directory}/conf/deploy.properties` contains properties values that must be updated for your system environment. These values are used during the installation step to indicate the location and version of software. . • **Note:** Do not modify the forward slashes (/) in the deploy.properties file, even when installing on Windows.

NOTE:	When entering information for use by the C3PR, no spaces are allowed in filenames or directory names.

Modifying the deploy.properties File in UNIX or Linux

The file {home_directory}/conf/deploy.properties contains property values that must be updated for your UNIX or Linux system environment. These values are used during the installation step to indicate the location and version of software. For example, make sure to update the pathnames to point to the location of MySQL, etc., on your computer.

Running the scripts to populate the database

Perform the following steps to populate the databases prior to building your system. The scripts are located in at the following location and should be run in the order below:
c3pr\database_scripts\

Step	Action
1	security_schema\security_tables_data_mysql.sql

This is a dump of a CSM Database from MySQL. There may be some protection elements that are not used. There is only a CSM user and no C3PR users. |
| 2 | c3pr_schema\ddls\oracle\tables.sql

This script will drop all objects in the C3PR Schema in the Oracle database and add them back in for a clean database. |
| 3 | c3pr_schema\referencedata\lookup_data.sql

This look up data is generic for the most part. It should be customized for your cancer center as indicated in Appendix I. |
| 4 | c3pr_schema\referencedata\protocols_data.sql

The application needs protocols to be interesting. Here is where you add the protocols. This file needs to be modified to add actual protocol data. |
| 5 | Now you are ready to build and deploy the application. |

Building a Demonstration System

Perform the following steps to build and deploy your system.

Step	Action

1	In a **Command Prompt** window, enter `cd {home_directory}` to go to your home directory (for example, in Windows `C:\C3PR`).
2	Enter `ant build-system`.
3	Deploy the .war file to the JBoss Server
4	Start JBoss
5	You are now ready to start. You will want to add users via the UPT with the required privileges. Refer to the Users Manual and the UPT documentation for guidance. Network security and SSL will also have to be installed, but are beyond the scope of this manual.

Contacting Technical Support

Application Support is available from the following:

C3PR Application Support

NCICB Application Support

Email: ncicb@pop.nci.nih.gov

Local: 301-451-4384

Toll-free: 888-478-4423

Web Site: http://ncicbsupport.nci.nih.gov

Appendix I Software and Documentation that is Included with the C3PR Application Download

The following software and documentation is included in the download package for C3PR:
- C3PR Source Code
- C3PR Oracle Database Load Scripts
- CSM Load Scripts
- C3PR Installation Manual

All other documentation is available in CVS at the following location:
http://cabigcvs.nci.nih.gov/viewcvs/viewcvs.cgi/c3pr/?cvsroot=opendevelopment

Appendix II Required C3PR Installation Script Modifications

The lookup values for the C3PR Application need to be tailored for each installation. The values should be changed in the look up tables' script during the installation. The following items should be modified for each installation:

Lookup Value: Protocol Type

Table: CODE_PROT_TYPE

Notes: We recommend the following values be added, but they are not used in any programming logic and can be modified to match the terminology currently used at your cancer center. The values below are associated with the C3PR model in the caDSR.

Code	Description
D	Diagnostic
GN	Genetic Non-therapeutic
GT	Genetic Therapeutic
N	Non-therapeutic
P	Primary Treatment
S	Supportive
T	Preventive

The lookup values for the C3PR Application need to be tailored for each installation. The values should be changed in the look up tables' script during the installation. The following items should be modified for each installation:

Lookup Value: Protocol Phase

Table: CODE_PROT_PHASE

Notes: We recommend the following values be added, but they are not used in any programming logic and can be modified to match the terminology currently used at your cancer center. The values below are associated with the C3PR model in the caDSR.

Code	Description
I	Phase I
I/II	Phase I/II
II	Phase II
III	Phase III
IV	Phase IV
NA	NOT APPLICABLE

Lookup Value: Protocol Status

Table: CODE_PROT_STATUS

Notes: We recommend the following values be added. The only status that is used by the application is Open. All other statuses are for information only. A protocol must be opened to register patients. If other statuses are used by your cancer center, they can be added with out affecting the application. The values below are associated with the C3PR model in the caDSR.

Code	Description
C	Closed
O	Open
S	Suspended
T	Terminated
I	IRB Approved

Lookup Value: Funding Source

Table: CODE_FUNDING_SOURCE

Notes: We recommend the following values be added. Other values can be added based on the insurance companies that the cancer center currently works with.

Code	Description
P	Private
M	Military
CG	Contract/Grant
OI	Other Insurance
SD	Special Discount Self Pay
CP	Custody Patients
OPP	Other Prepaid Health Plans
SP	Self-Pay
WC	Workman's Compensation
CI	Commercial Insurance
U	Unknown
F	Funded
MP	Medicare/Pending

Lookup Value: Not Count Towards Accrual Reason

Table: CODE_NOT_COUNT_ACCRUAL_REASON

Notes: We recommend the following values be added. Other values can be added based on the reasons that the cancer center considers acceptable for not counting a patient towards accrual.

Code	Description
UE	User Error
MI	Mistaken Identity
OT	Other

The following tables may need to be updated with additional values for your cancer center. The caDSR should be used to determine the appropriate values:
1. COUNTRY
This table can be updated with any countries you expect to use in patient addresses.

2. ORGANIZATION

This table contains three types of originations:

IC: These are the available Primary ID Sources (places where the Primary ID was assigned i.e., the medical record number).

BR: Stands for Branch (or Department). At least one Branch is required.

SR: Sponsor is used to identify available Protocol Sponsors

3. CODE_REASON

The reasons and codes should match up with C3D values.

4. CONFIGURATION_PARAMETERS

There are several configuration parameters stored in the database. These are mostly required for operation or at least proper look and feel.

C3DURL – The URL for the C3D instance used by C3PR

ApplicationLogo – This is the location of the logo that appears on all the pages

ApplicationLongTitle - The title of the Application. Example: Cancer Clinical Central Participant Registry.

ApplicationAbbrTitle - The title of the Application. Example: C3PR.

HomeWhatsNew - HTML Text for the What's New Section of the Application Home Page.

HomeDidYouKnow – HTML Text for the Did You Know Section of the Application Home Page.

ContactUsDetail – HTML Text for the Contact Us Page.

PrivacyDetail1 - HTML Text for the Privacy Notice Page. Please note: There are 5 records for entering PRIVACY Notice Html text so that content can fit if more than 4000 characters.

PrivacyDetail2 - HTML Text for the Privacy Notice Page continued. Please note: There are 5 records for entering PRIVACY Notice Html text so that content can fit if more than 4000 characters.

PrivacyDetail3 - HTML Text for the Privacy Notice Page continued. Please note: There are 5 records for entering PRIVACY Notice Html text so that content can fit if more than 4000 characters.

PrivacyDetail4 - HTML Text for the Privacy Notice Page continued. Please note: There are 5 records for entering PRIVACY Notice Html text so that content can fit if more than 4000 characters.

PrivacyDetail5 - HTML Text for the Privacy Notice Page continued. Please note: There are 5 records for entering PRIVACY Notice Html text so that content can fit if more than 4000 characters.

ReportsDesignation - Reports Designation. For Application Reports use href = "reportsMenu.do". For external application reports provide a URL. This controls where you go when you click the Reports tab.

DisclaimerDetail1 – HTML Text for Disclaimer Page. Please note: if more than 4000 characters, use respective sequential records to provide content.

DisclaimerDetail2 – HTML Text for Disclaimer Page continued. Please note: if more than 4000 characters, use respective sequential records to provide content.

DisclaimerDetail3 – HTML Text for Disclaimer Page continued. Please note: if more than 4000 characters, use respective sequential records to provide content.

HomeApplicationDescription – HTML text for Application Description on Application Home Page.

AccessibilityDetail1 – HTML Text for accessibility Page. Please note: if more than 4000 characters, use respective sequential records to provide content.');

AccessibilityDetail2 – HTML Text for accessibility Page continued. Please note: if more than 4000 characters, use respective sequential records to provide content.');

AccessibilityDetail3 – HTML Text for accessibility Page continued. Please note: if more than 4000 characters, use respective sequential records to provide content.');

ApplicationSupportDetail – HTML Text for App Support Page.

LinksPageDetail – HTML content for Links Page.

NCIAdopterLogoText - The ALT text for the Adopter Logo Text.

NCIAdopterTagLineText - The ALT text for the Adopter Logo Tag Line Text.

NCIAdopterURL - The ALT text for the Adopter Logo URL.

ShowFooter - Y or N value allowed. Show NCI footer or not.

AuthenticationType - The type of the authentication.

NCIAdopter – Adopter, for example "NCI" or "LOMBARDI"

CADSRURL - caDSR URL

DBType – Database type for example: Oracle Database

HelpLink - Help Designation. For User manual provide the docs/C3PR_Users_Guide.pdf.

HelpWithoutLink - Help Designation without login. For User manual provide the docs/C3PR_Users_Guide.pdf.

ReferralLetterTextLine - This is text for the Referral Letter report. This is line 1 of the report. This line contains tokens {patientName] and {primaryIdSource}.

ReferralLetterTextLine2 - This is text for the Referral Letter report. This is line 2 of the report.

ReferralLetterTextLine3 - This is text for the Referral Letter report. This is line 3 of the report.

ReferralLetterFromName - This is text for the Referral Letter report. This is value for from/name element.

ReferralLetterFromTitle - This is text for the Referral Letter report. This is value for from/title element.

OPADBSID - OPA Development database SID

Appendix III SQL Server Installation

The following changes are required for SQL Server Installation:
•   Use SQL Server Scripts
•   Create a database in SQL Server
•   Identify the correct JBoss Data Sources
•   Obtain the SQL Server JDBC Driver

     2/9/2007